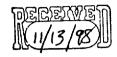




8408 '98 NOV 18 P2:16

November 15, 1998



The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Standard Process offers many products that will help support your immune system from the stresses of modern life and the changing seasons.*
- (2) Immuplex supports the entire immune system by nourishing each of the organs and tissue systems that work together in the body's immune alliance. Immuplex contains Thymus PMG and zinc for thymus support and white blood cell production; selenium, a constituent of three important anti-oxidant enzymes; vitamin B₆, an essential component of two key immune system substances; and vitamin C for normal immune maintenance.*

These statements are made for a dietary supplement containing bovine liver PMG Extract, zinc-iron-copper liver chelate, bovine liver powder, veal bone PMG Extract, ascorbic acid, nutritional yeast, bovine spleen PMG Extract, high selenium yeast, vacuum dried bovine and ovine spleen, bovine thymus PMG Extract, bovine thymus Cytosol Extract, mixed tocopherols, high chromium yeast, pyridoxal 5-phosphate, vitamin A esters, calcium lactate, folic acid, and cyanocobalamin. The name of the product is Immuplex®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

Cenn M. Wolden

97S - 0162

LETZYYY

